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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,007	08/17/2001	Daniel Scherman	03806-0512	2754

7590 10/01/2002

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EXAMINER	
CHEN, LIPING	
ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,007	SCHERMAN ET AL.	
	Examiner	Art Unit	
	Liping Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-112 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-112 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9-11, 14-28, 30-39, 41-43 or 44-55, 57-59, 62-70 and 72-77, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

II. Claims 1-4, 8, 9-11, 14-28, 30-39, 41-43 or 44-52, 56-59, 62-70 and 72-77, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

III. Claims 1-7, 9, 12, 13, 14-28, 30-39, 41-43 or 44-55, 57, 60-70 and 72-77, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

IV. Claims 1-4, 8, 9, 12, 13, 14-28, 30-39, 41- 52, 56, 57, 60-70 and 72-77, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

V. Claims 1-7, 9-11, 14-24, 29, 30-37, 41-55, 57-59, 62-66, 71 and 72-75, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a bacterium or parasite vector, a method for regulating the expression of the transgene in the target tissue or cell, classified in 435, subclass 69.1.

VI. Claims 1-4, 8, 9-11, 14-24, 30-37, 41-52, 56-59, 62-66 and 72-75, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a bacterium or parasite vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

VII. Claims 1-7, 9, 12, 13, 14-24, 30-37, 41-55, 57, 60-66 and 72-75, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence

of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a bacterium or parasite vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

VIII. Claims 1-4, 8, 9, 12, 13, 14-24, 30-37, 41-52, 56, 57, 60-66 and 72-75, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a bacterium or parasite vector, a method for regulating the expression of the transgene in the target tissue or cell of nonhuman animal or human origin, classified in 435, subclass 69.1.

IX. Claims 1-7, 9-11, 14-28, 30-37, 40-55, 57-59, 62-70, 72-75 and 78, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of plant origin, classified in 435, subclass 69.1.

X. Claims 1-4, 8, 9-11, 14-28, 30-37, 40- 52, 56-59, 62-70, 72-75 and 78, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARα, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a plasmid or viral vector, a method for regulating the

expression of the transgene in the target tissue or cell of plant origin, classified in 435, subclass 69.1.

XI. Claims 1-7, 9, 12, 13, 14-28, 30-37, 40-55, 57, 60-70, 72-75 and 78, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence of an inhibitory transgene under the control of a repressible promoter which comprise at least one repeat of the tetracycline response operator or an activatable autocatalytic aptamer sequence, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of plant origin, classified in 435, subclass 69.1.

XII. Claims 1-4, 8, 9, 12, 13, 14-28, 30-37, 40-52, 56, 57, 60-70, 72-75 and 78, drawn to a composition comprising a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript under the control of PPARγ, and a second nucleic acid comprising a sequence of an inhibitory transgene which also comprises a sequence can be recognized by a ribozyme, a plasmid or viral vector, a method for regulating the expression of the transgene in the target tissue or cell of plant origin, classified in 435, subclass 69.1.

XIII. Claims 46 and 79-100, drawn to a pharmaceutical composition comprising the composition which comprises a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript and a second nucleic acid comprising a sequence of an inhibitory transgene, and a method for manufacturing a medicinal product, classified in 514, subclass 44.

XIV. Claims 101-106, drawn to a transgenic animal, which carries a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript and a second nucleic acid comprising a sequence of an inhibitory transgene, each of the sequences are

under the control of separated transcriptional promoters, and both activities are regulated by at least one external agent, classified in 800, subclass 8^{+}.

XV. Claims 107-112, drawn to a transgenic plant, which carries a first nucleic acid comprising a sequence of a transgene of interest encoding a transcript and a second nucleic acid comprising a sequence of an inhibitory transgene, each of the sequences are under the control of separated transcriptional promoters, and both activities are regulated by at least one external agent, classified in 800, subclass 295^{+}.

In addition, upon the election of any of groups 1-XII, further election of the following patentably distinct species of the claimed invention is required:

I) Inhibitory transcript: an antisense RNA, an RNA capable of forming a triple helix with a portion of the nucleic acid, or a ribozyme.

II) Method of introducing the nucleic acids into target tissue or cell: a physical/mechanical method, or a chemical/biochemical agent.

III) Administration methods: systemically, or local (such as topically cutaneously) injection.

The inhibitory transcripts are distinct because they are structurally, functionally distinct.

The method of introducing the nucleic acids into target tissue or cell and the administration methods are distinct because they differ at least in method steps, reagents, dosages, schedules used, response variables and criteria for success.

The inventions are distinct, each from the other because:

Inventions I-IV are directed to a composition or method where the target tissue is tissues or cells of animal.

Inventions V-VIII are directed to a composition or method where the target tissue is bacterium or parasite vectors.

Inventions IX-XII are directed to a composition or method where the target tissue is tissues or cells of plant origin.

Inventions I-XII are directed to patentably distinct inventions as they are different in the composition. Inventions I, II, V, VI, IX and X each comprise a first nucleic acid under the control of PPARα promoter, however, inventions I, V and IX each comprises inhibitory transgene under the control of a repressible promoter or autocatalytic aptamer sequence, while invention II, VI and X each comprises inhibitory transgene that also comprises a sequence can be recognized by a ribozyme; Inventions III, IV, VII, VIII, XI and XII each comprise a first nucleic acid under the control of PPARγ promoter, however, inventions III, VII and XI each comprises a inhibitory transgene under the control of repressible promoter or autocatalytic aptamer sequence, while inventions IV, VIII and XII each comprises inhibitory transgene that also comprises a sequence can be recognized by a ribozyme.

Inventions I-XII and invention XIII are distinct as the method for regulating the expression of a transgene of interest *in vivo* of invention I-XII are not needed for the implementation the method for manufacturing a medicinal product of invention XIII, and vice versa. Each of the methods requires a separate and materially different protocol.

Inventions I-IV and Invention XIV are distinct products capable of separate use. Although the vectors of invention I-IV can be used for making transgenic animal of invention XIV, they can also be used for *in vitro* transgene regulation study or protein production. The tissues or cells containing expression vectors of invention I-IV do not need to be genetic modified while the transgenic animal of invention XIV is genetic modified, which can be used as treatment model. Furthermore, the cells and tissues of inventions I-IV are structurally, functionally different with the transgenic animal of invention XIV.

Inventions V-XII and Invention XIV are mutually exclusive and independent. The bacterium vectors of inventions V-VIII and plant vectors of inventions IX-XII are not needed for the implementation

of trangenic animal of invention XIV, and vice versa. Each of the invention requires a separate and materially different protocol.

Inventions I-VIII and Invention XV are mutually exclusive and independent. The animal cell or tissue of inventions I-IV and bacterium vectors of inventions V-VIII are not needed for implementation of the transgenic plant of invention XV, and vice versa. Each of the invention requires a separate and materially different protocol.

Inventions IX-XII and invention XV are distinct products capable of separate use. Although the vectors of invention IX-XII can be used for making transgenic plant of invention XV, they can also be used for *in vitro* transgene regulation study. The tissues or cells containing expression vectors of invention IX-XII do not need to be genetic modified while the transgenic plant of invention XV is genetic modified. Furthermore, the cells and tissues of inventions IX-XII are structurally, functionally different with the transgenic plant of invention XV.

Invention XIII and either of inventions XIV and XV are mutually exclusive and independent. The method for manufacturing a medicinal product of invention XIII is not needed for implementation of the trangenic animal of invention XIV, or the transgenic plant of invention XV, and vice versa. Each of the invention requires a separate and materially different protocol.

Invention XIV and invention XV are mutually exclusive and independent. The transgenic animal of invention XIV is not needed for implementation of the transgenic plant of invention XV, and vice versa. Each of the invention requires a separate and materially different protocol.

Note: Misnumbered claims 77-113 been renumbered 76-112 (Rule 1.126).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

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Group 1632

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